

Analgesic Benefit of PECS Blocks for Biceps Tenodesis Shoulder
Surgery
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Study Title: Analgesic Benefit of PECS Blocks for Biceps Tenodesis Shoulder Surgery

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Sponsor: Department of Anesthesiology, Wake Forest Baptist Health

Background, Rationale and Context

The standard practice for arthroscopic shoulder surgery at our institution is a general anesthetic with a long-acting interscalene block for post-operative pain control, which can reduce the amount of opiates needed after surgery.¹ The interscalene block is effective in providing analgesia to the majority of the shoulder joint and has been shown to reduce post-operative pain scores after arthroscopic shoulder surgeries.² However, there is a subset of arthroscopic shoulder surgery patients who have pain in the axilla even in the setting of a functioning interscalene brachial plexus nerve block. One of our surgeons has reported a high incidence of axillary pain in patients who undergo a sub-pectoral biceps tenodesis as part of their arthroscopic procedure. A newly described nerve block approach to the nerves that supply sensation to the axillary region called the PECS 1 & 2 block may provide additional analgesia to these patients.^{3,4}

Objectives

The purpose of this prospective, randomized, observer and patient blinded, single-center, sham block trial is to determine if the addition of PECS blocks to an interscalene block will reduce the severity of axillary pain following arthroscopic shoulder surgery that involves a sub-pectoral biceps tenodesis. Secondly, the study will assess the duration of PECS 1 & 2 and whether the block reduces post-operative opioid usage. We hypothesize that the addition of the PECS 1 & 2 block will reduce the severity of axillary pain at 6hrs and reduce postoperative narcotic usage for the first 24 hours.

Methods and Measures

Design

Subjects that meet the inclusion criteria will be assigned a group by using a random numbers generator. All subjects will receive the standard practice at our institution of an interscalene brachial plexus block along with a general anesthetic. The intervention arm will get an additional local anesthetic block targeting nerves that we presume cover the axillary region (PECS 1 & 2). These nerves in the upper chest are the lateral branches of the T2 to T5 intercostal nerves, which includes the intercostobrachial nerve. The anesthesiologist placing the nerve blocks will be unblinded to perform the procedures. Both the surgeon and the Acute Pain Service anesthesiologist will be blinded as to whether or not the intervention was provided to any given subject. The Acute Pain Service team will remain blinded and collect the data outcomes.

Setting

Subjects undergoing arthroscopic shoulder surgery with a sub-pectoral biceps tenodesis, by a single surgeon at our institution, will be assessed either in person or by phone to obtain postoperative pain data. Post-operative ambulatory surgery subjects will be asked 6 hours after block placement about the presence of axillary pain at rest and the Numerical Rating Scale pain score (0-10) will be recorded as the primary outcome. Secondary endpoints will include, but are not limited to; total narcotic usage, presence of nausea or vomiting through the first 24hrs, as well as time to return of axillary pain. These outcomes will be assessed by phone call on post-op day 1.

Protocol version:

Template updated 9.24.14

Subjects selection criteria

Subjects presenting to Wake Forest Baptist Hospital for shoulder arthroscopy with sub-pectoral biceps tenodesis will be eligible for this study.

- **Inclusion Criteria**

Adults, between 18 and 90 years of age who have agreed to a regional with general anesthesia technique will be recruited to participate.

- **Exclusion Criteria**

Subjects with contraindications to regional anesthesia, such as history of allergy to amide local anesthetics, presence of a progressive neurological deficit, a pre-existing coagulopathy, infection, significant pulmonary disease contraindicating phrenic nerve blockade (a known side effect of an interscalene block) or the following conditions: chronic use of an opioid analgesic (>3 months of a combined total of more than 40mg oxycodone equivalents a day), body habitus that makes successful placement of PECS blocks unlikely or pregnancy.

- **Sample Size**

Initially, pilot data was collected in a total of ten patients with five patients randomized to each arm. Primary endpoint was Numerical Rating Scale (NRS) of 0-10 at 6hrs after block placement. Our pilot data indicate that the mean NRS is about 5 for the control group, with a standard deviation of 1.4. Using a two-sided two-sample t test (an alpha of 0.05 and power of 0.95), we conservatively estimate that 14 subjects per arm will be needed to detect a clinically meaningful difference of 2 in NRS between the arms. We decided to plan enrollment of 20 subjects per arm for potential loss during this randomized, double-blinded, single-center, sham block trial.

Interventions and Interactions

- All patients scheduled by Dr. Freehill for arthroscopy with biceps tenodesis surgery will be given the PECS Study Consent Form during the orthopedic clinic visit for review. The study team will then examine the electronic medical record of these potential subjects for exclusion criteria. If the subject is excluded, then they will be added to the Screening Log with date and reason for their exclusion. If all inclusion criteria are met, then the subject will be approached in the Regional Anesthesia area on the day of surgery for further discussion of the study protocol. Upon completion of consent, one signed copy will remain with the subject while a second signed document will be maintained by the study team in the research files.
- Patients will be asked to provide baseline verbal pain scores both, at rest and with movement, on a scale of 0-10 (0 being no pain and 10 being the worst pain). Preoperative opioid use including drug(s), dosage and frequency will be recorded. Randomization of patients will then occur through the use of sequentially numbered envelopes with only those directly involved in the care of the patient during block placement being aware of which arm of the study the patient has been randomized. Those members of the study team who will be collecting post-operative data will be blinded to the randomization.
- Standard ASA monitors and oxygen will be applied. Unless there is a contraindication, each patient will receive 650mg of PO acetaminophen. To standardize the effect on postoperative pain, ketamine will not be given as a preoperative sedation medication or intraoperative medication. No long acting opioids will be given in the operating room or PACU.

Intraoperative fentanyl will be limited to 5 micrograms per kg. Intraoperative dexamethasone will not be given for PONV prophylaxis.

- Subjects will be sedated as per usual practice and will also be blinded to their randomization. All peripheral nerve blocks will be performed by a resident or fellow under supervision by an attending anesthesiologist. The attending anesthesiologist may perform the procedures alone. All volumes and concentrations of nerve block mixtures administered will be identical to assist in the blinding process.
- All 40 subjects will receive an ultrasound guided interscalene nerve block using 20mL of 0.25% bupivacaine with 1:400k epinephrine and 1:600k clonidine dosed at the upper trunk location near the C6 vertebral level, per standard clinical practice. The intervention arm, consisting of 20 patients, will additionally receive the following: 10mL of 0.25% bupivacaine with 1:400k epinephrine and 1:600K clonidine at the PECS1 location and 20mL of 0.25% bupivacaine with 1:400k epinephrine and 1:600k clonidine at the PECS2 location as described by Blanco, et al.^{3,4}
- All procedures will be performed under a sterile technique including the use of chlorhexidine prep of the skin, sterile gloves, sterile ultrasound probe covers with sterile ultrasound gel, a cap and a mask. For the interscalene block, a 21 gauge 90mm stimulating block needle will be directed, under real-time ultrasound guidance, into the interscalene muscle space at the level of the C5 and C6 nerve roots. Twenty mL of the above local anesthetic mixture will be dosed incrementally, aspirating every 5 mL, to surround the upper trunk of the brachial plexus. For the PECS 1 & 2 block, a 21 gauge 90mm stimulating block needle will be placed under real-time ultrasound guidance at approximately the level of the 4th and 5th ribs near the mid-axillary line. The needle will be advanced into a tissue plane between the serratus anterior muscle and the pectoralis minor muscle. Twenty mL of the same local anesthetic mixture will be dosed incrementally, every 5 mL, to spread within this PEC2 space. The needle will be withdrawn, following the first injection, to a tissue plane between the pectoralis minor and pectoralis major muscles. Ten mL of the same local anesthetic mixture will be dosed incrementally, every 5 mL, to spread within this PEC1 space.
- Fifteen and 30 minutes (if no change at 15min) following block placement, success will be assessed by absence/decrease of pin-prick sensation to a 25gauge Whitacre needle in the following manner:
 - Cutaneous sensation will be tested over the deltoid region to assess for successful interscalene block.
 - Cutaneous sensation will be tested over the lateral aspect of the pectoralis muscles at the level of the nipple.
 - Scoring of sensation will be the following: 0= full sensation, 1= partial sensation, 2= no sensation (complete block)
- Following block placements, the subjects will be transported to the OR and general anesthesia will be induced. Following intubation, surgical procedure, emergence and extubation, the subject will be transported to the recovery room. In the recovery room or via phone post-discharge, at the 6hr mark post-block placement, we will ask the subject if they are having any axillary pain. The severity of pain will be determined using the Numerical Rating Scale of 0-10. Zero is no pain and 10 is the most pain possible. Total opiate and benzodiazepine doses will be charted for the Pre-Op, Intra-Op and PACU time frames.
- Expected time commitment for the subjects is the following: (40 minutes total)
 - Enrollment- 15 minute discussion and signing of documents
 - Block placement and assessment- 15 minutes more than non-participants (additional 2 injections)
 - Recovery room data collection- 5 minutes
 - Postop day 1 phone call data collection- 5 minutes

- Schedule of Events
 - 0-1 hours: Enrollment, consent, block placement and assessment
 - 1-4 hours: Typical operating room time for surgery
 - 4-5 hours: Typical recovery room times
 - Hour 6: Assessment in recovery room or via phone.
 - Hour 24: Phone call for data collection. Termination of the study.

Outcome Measure(s)

Primary: Post-operative ambulatory surgery subjects will be asked 6 hours after block placement about the presence of axillary pain at rest. Visual analog pain scores (0-10) will be recorded with 0= no pain, 10=most pain possible.

Secondary: These endpoints will include, but are not limited to; total narcotic usage, VAS pain scores at rest at 24hrs, the presence of nausea or vomiting through the first 24hrs and the time to return of axillary pain. These outcomes will be assessed by phone call on the morning of post-op day 1.

Analytical Plan

Results will be analyzed initially using descriptive statistics for baseline characteristics. The primary outcome VAS will be analyzed using a two sample t test. In the situation where the primary outcome VAS is highly skewed, we will use a non-parametric Wilcoxon Rank Sum test to determine the intervention effect. For secondary outcomes, comparison between groups will be done using chi square tests for proportions, and two sample t-tests for continuous variables.

Human Subjects Protection

Subject Recruitment Methods

The subject will be identified by examining the operating room schedule and the surgeon's notes for shoulder arthroscopy procedures with a sub-pectoral biceps tenodesis component. Assuming the subjects meet inclusion criteria, they will be assigned to the Regional Anesthesia area and any of the following will enroll the subjects: Wells Reynolds, MD, Sean Dobson, MD, Chris Edwards, MD, Daryl Henshaw, MD, Doug Jaffe, DO, or Robert Weller, MD. The subjects will be contacted via phone with numbers provided during recruitment. Both genders will be included equally and only exclusion criteria noted earlier will be used. The recruitment of potential subjects will only be evident by a marking on the operating room schedule, within the secure electronic medical record, that denotes their assignment to the Regional Anesthesia Pre-operative area. This marking does not identify the subjects as research study candidates.

- For studies using PHI to identify subjects via medical records search or referral from a treating physician, who will then be contacted, you will need a limited waiver of HIPAA authorization. If this applies to your study, please provide the following information:
 - Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. What information are you planning to collect for this purpose?
 - We will need to review the Surgeon's note to determine if the potential subjects are having a sub-pectoral biceps tenodesis component to their surgery.
 - How will confidentiality/privacy be protected prior to ascertaining desire to participate?
 - Both the operating room schedule and Surgeon's notes are contained in a secured, electronic medical record keeping system called Epic.

- When and how will you destroy the contact information if an individual declines participation?
 - No contact information will be kept other than a screening log with gender, race and date of screening. This will be kept secured with other Study records.

Informed Consent

- Signed informed consent will be obtained from each subject by any of the following Investigators: Wells Reynolds, MD, Sean Dobson, MD, Chris Edwards, MD, Daryl Henshaw, MD, Doug Jaffe, DO, or Robert Weller, MD. Consent will be obtained in the Regional Anesthesia Area adjacent to the Operating Room on the morning of surgery.
- The most recent IRB approved informed consent form will be used to obtain informed consent from potential research subjects. This will be identified by a version date and an expiration date in the footer.
- The person obtaining informed consent will introduce themselves to the potential subject and discuss the following:
 - Explanation of what the clinical research study is and why you are approaching them.
 - What they can expect if they choose to participate in the research study.
 - How participation affects their regular care.
- Ample time will be given for the subject to read and/or listen to the consent form being read or reviewed with them and to ask any questions.
- All questions will be answered fully by the person obtaining informed consent.
- The person obtaining informed consent will acknowledge that the potential subject has an understanding of the research and research related procedures that are to be done.
- The person obtaining informed consent will sign and date the last page of the consent form.
- A copy of the fully signed consent form will be given to the subject and the original will be filed in the subject's research file.
- Written informed consent will be obtained before any research related procedures are performed.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed within 3 years of closing the study consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

1. Chen HP, Shen SJ, Tsai HI, Kao SC, Yu HP. Effects of Interscalene Nerve Block for Postoperative Pain Management in Patients after Shoulder Surgery. *Biomed Res Int.* 2015;2015:902745.
2. Zoremba M, Kratz T, Dette F, Wulf H, Steinfeldt T, Wiesmann T. Supplemental Interscalene Blockade to General Anesthesia for Shoulder Arthroscopy: Effects on Fast Track Capability, Analgesic Quality, and Lung Function. *Biomed Res Int.* 2015;2015:325012.
3. Blanco R. The 'pecs block': a novel technique for providing analgesia after breast surgery. *Anaesthesia.* 2011 Sep;66(9):847-8.
4. Blanco R, Fajardo M, Parras Maldonado T. Ultrasound description of Pecs II (modified Pecs I): a novel approach to breast surgery. *Rev Esp Anesthesiol Reanim.* 2012 Nov;59(9):470-5.

Appendix

1. Data collection form
2. Consent form if one will be used